

We Claim:

1. A patch for transcutaneous immunization comprised of the following:
 - (a) a dressing,
 - (b) an antigen, and
 - (c) an adjuvant;

wherein at least one of the antigen and the adjuvant ingredients is in dry form, and whereby application of the patch to intact skin induces an immune response specific for the antigen.

2. A method of inducing an immune response using a formulation as in Claim 1 comprising applying a formulation to intact skin of a subject, wherein the formulation is comprised of antigen and adjuvant ingredients, and at least one of the antigen and the adjuvant ingredients is in dry form; and thereby inducing the immune response specific for the antigen.

3. The method of Claim 2, wherein the formulation is applied with an occlusive dressing.

4. The method of Claim 3, wherein the occlusive dressing covers a surface area of the intact skin which is larger than at least one draining lymph node field.

5. The method of Claim 2, wherein the formulation consists essentially of antigen and adjuvant.

6. The method of Claim 2, wherein at least one adjuvant is an ADP-ribosylating exotoxin.

7. The method of Claim 2, wherein at least one adjuvant is selected from the group consisting of unmethylated CpG dinucleotides, lipopolysaccharides, and cytokines.

8. The method of Claim 2, wherein at least one adjuvant is provided in the formulation as a nucleic acid.

9. The method of Claim 8, wherein the nucleic acid is a non-integrating and non-infectious plasmid.
10. The method of Claim 2, wherein at least one antigen has a molecular weight greater than 500 daltons.
11. The method of Claim 2, wherein at least one antigen is derived from a pathogen selected from the group consisting of bacterium, virus, fungus, and parasite.
12. The method of Claim 2, wherein at least one antigen is a tumor antigen or an autoantigen.
13. The method of Claim 2, wherein at least one antigen is selected from the group consisting of carbohydrate, glycolipid, glycoprotein, lipid, lipoprotein, phospholipid, and polypeptide.
14. The method of Claim 2, wherein the formulation is comprised of an attenuated live virus and at least one antigen is expressed by the attenuated live virus.
15. The method of Claim 2, wherein at least one antigen is a polypeptide of greater than 500 daltons molecular weight.
16. The method of Claim 2, wherein at least one antigen is multivalent.
17. The method of Claim 2, wherein at least one antigen is provided in the formulation as a nucleic acid encoding a polypeptide.
18. The method of Claim 17, wherein the nucleic acid is a plasmid.
19. The method of Claim 2, wherein a single molecule is both an adjuvant and an antigen of the formulation.

20. The method of Claim 2, wherein antigen and adjuvant are both provided in dry form in the formulation.

21. The method of Claim 2, wherein at least one adjuvant is provided in dry form.

22. The method of Claim 2, wherein at least one antigen is provided in dry form.

23. The method of Claim 2, wherein application of the adjuvant to the intact skin activates an underlying Langerhans cell.

24. The method of Claim 2, wherein application of the adjuvant to the intact skin causes an underlying Langerhans cell to increase major histocompatibility complex class II expression.

25. The method of Claim 2, wherein application of the adjuvant to the intact skin causes migration of an underlying Langerhans cell to a lymph node.

26. The method of Claim 2, wherein application of the adjuvant to the intact skin signals an underlying Langerhans cell to mature into an antigen presenting cell.

27. The method of Claim 2, wherein application of the adjuvant to the intact skin enhances antigen presentation to lymphocytes.

28. The method of Claim 2, wherein the immune response is not an allergic reaction.

29. The method of Claim 2, wherein the immune response is comprised of an antigen-specific lymphocyte.

30. The method of Claim 2, wherein the immune response is comprised of an antigen-specific antibody.

31. The method of Claim 2 further comprising applying alcohol to the intact skin prior to application of the formulation.

32. The method of Claim 2 further comprising hydrating the intact skin prior to application of the formulation.

33. The method of Claim 2 further comprising dissolving at least one dry ingredient of the formulation such that a solution saturated for the dissolved ingredient is placed in contact with the intact skin.

34. The method of Claim 33, wherein the formulation is further comprised of an immunologically-inactive polymer that reduces the dissolved ingredient's saturation concentration in the solution.

35. The method of Claim 2, further comprising physically or chemically penetrating the previously intact skin at a site of application of the formulation to enhance immunization.

36. The method of Claim 2, wherein a physical, chemical, electrical, or sonic penetration enhancer is not involved in application of the formulation.

37. The method of Claim 2, wherein the formulation does not include a penetration enhancer, viral particle, liposome, or charged lipid.

38. A method of immunization comprising applying a dry formulation to skin of a subject, wherein the dry formulation comprises antigen and adjuvant as active ingredients, in an amount and for a time sufficient to induce a systemic or regional immune response, or both, specific for the antigen.

39. A method of inducing an immune response using a formulation as in Claim 1 comprising:

- (a) applying at least one antigen epicutaneously on a subject,
- (b) activating a Langerhans cell underlying the skin with at least one adjuvant,
- (c) signaling the Langerhans cell to migrate to a lymph node of the subject and mature into an antigen presenting cell, and
- (d) presenting the antigen on a cell surface of the antigen presenting cell to a lymphocyte; thereby inducing the immune response in the subject, wherein at least one of the antigen and the adjuvant is provided in dry form, and wherein the immune response is specific for the antigen.

40. A method of inducing an immune response using a formulation as in Claim 1 comprising:

- (a) applying a formulation to intact skin of a subject, wherein the formulation comprises (i) a nucleic acid containing a sequence encoding the antigen and (ii) an adjuvant; and
- (b) inducing the immune response in the subject without perforating the skin, wherein at least one of the nucleic acid and the adjuvant is applied in dry form, and wherein the immune response is specific for the antigen.

41. A method of producing a formulation for transcutaneous immunization comprising in any order:

- (a) providing at least two active ingredients of the formulation, wherein at least one active ingredient is an antigen and at least one active ingredient is an adjuvant;
 - (b) dissolving at least one of the active ingredients in a liquid;
 - (c) drying the liquid on a solid substrate; and
 - (d) combining the active ingredients together to produce the formulation;
- wherein at least one of the formulation's active ingredients is dry at least until the formulation is applied to skin of a subject to be immunized.

42. The method of Claim 41 further comprising mixing all active ingredients together to produce a homogeneous formulation.

43. The method of Claim 41, wherein the solid substrate is a dressing and the formulation is thereby provided as a patch.

44. The method of Claim 41, wherein a single application of the formulation to the subject's skin is sufficient to induce a detectable antigen-specific immune response.

45. The method of Claim 41, wherein the formulation is further comprised of at least one excipient, stabilizer, dessicant, or preservative.